



Since January 2020 Elsevier has created a COVID-19 resource centre with free information in English and Mandarin on the novel coronavirus COVID-19. The COVID-19 resource centre is hosted on Elsevier Connect, the company's public news and information website.

Elsevier hereby grants permission to make all its COVID-19-related research that is available on the COVID-19 resource centre - including this research content - immediately available in PubMed Central and other publicly funded repositories, such as the WHO COVID database with rights for unrestricted research re-use and analyses in any form or by any means with acknowledgement of the original source. These permissions are granted for free by Elsevier for as long as the COVID-19 resource centre remains active.

comparison correctly reflects the available data. Ongoing real-world experience with AVA among ERT-experienced patients from managed access programs and registries will provide additional evidence.

CO123

HEALTH-RELATED QUALITY OF LIFE (HRQOL) AMONG MUCOPOLYSACCHARIDOSIS (MPS) PATIENTS RECEIVING ENZYME REPLACEMENT THERAPY (ERT): A SYSTEMATIC LITERATURE REVIEW

Druyts E, Li J, Mynzhassarova A, Yan K

Pharmalytics Group, Vancouver, BC, Canada

Objectives: To assess the HRQoL of MPS patients on ERT in clinical trials and real-world observational studies. **Methods:** A systematic literature search (SLR) was conducted using EMBASE and MEDLINE to assess HRQoL of MPS patients receiving ERT. Eligible studies included clinical trials or observational studies. **Results:** The SLR identified 870 studies of which five studies evaluated the impact of ERT on HRQoL. Three studies reported HRQoL in patients with MPS IV and one each assessed HRQoL in patients with MPS I, II, and VI. The number of patients in each study ranged from 7 to 68. Instruments used to report HRQoL included EQ-5D (n=4), SF-36 (n=2), TACQOL/TAPQOL (n=1), and PedsQL (n=2). HRQoL of patients were assessed by caregivers in two studies and by self-assessment in three studies. Harmatz et al 2016 reported the SF-36 physical component scores (PCS) remained unchanged after 48 weeks of ERT in seven MPS IV patients and decreased in one patient. Wyatt et al 2012 reported a significant change in HRQoL up to 8 years of ERT treatment in 39 patients with MPS II, but no significant change was observed in MPS I patients. Pintos-Morell et al 2018 reported 3 of 6 MPS IV patients treated with ERT had improved EQ-5D scores after 8 months. In Cleary et al 2021, 55 MPS IV patients treated with ERT reported no significant change in EQ-5D scores after three years. Brands et al 2013 reported 11 MPS VI patients had a decreased in TACQOL/TAPQOL anxiety and negative emotions after 2.5 years on ERT. **Conclusions:** Moderate improvements in HRQoL were observed in patients receiving ERT. There is a dearth of evidence of HRQoL among MPS patients particularly those receiving non-ERT based treatments.



CO124

REAL-WORLD REDUCTION OF ORAL CORTICOSTEROID USE IN PATIENTS TREATED WITH DUPILUMAB AND WITH MODERATE-TO-SEVERE ASTHMA

Pawar A,¹ Blaiss MS,² Modena BD,³ Khan AH,⁴ Gómez LDP,⁵

Pandit-Abid N,⁶ Radwan A,⁷ Jacob-Nara JA⁶

¹Sanofi, Cambridge, MA, USA, ²Medical College of Georgia at Augusta

University, Augusta, GA, USA, ³Modena Allergy & Asthma, La Jolla, CA, USA,

⁴Sanofi, Chilly-Mazarin, France, ⁵Sanofi, Madrid, Spain, ⁶Sanofi, Bridgewater,

NJ, USA, ⁷Regeneron Pharmaceuticals, Inc., Tarrytown, NY, USA

Objectives: Dupilumab, a fully human monoclonal antibody, blocks the shared receptor component for interleukin-4/-13, key and central drivers of type 2 inflammation in asthma. Patients with oral corticosteroid (OCS)-dependent severe asthma are at increased risk of OCS-related adverse events. This real-world analysis investigated the reduction in OCS use in patients treated with dupilumab, both overall cohort and with OCS-dependent severe asthma. **Methods:** This was a retrospective, single-arm study of data from the US insurance claims database Avalere and included patients with moderate-to-severe asthma initiating dupilumab treatment. OCS use was examined during the 12-month baseline period and the 12-month follow-up after starting dupilumab. The number of days of OCS use, proportion of patients who used any OCS and who used OCS on ≥ 90 days, and cumulative OCS dose were evaluated. **Results:** Of 780 patients overall, 141 were OCS-dependent at baseline. Mean (SD) annualized cumulative dose of OCS during the baseline period was 3485.5 (3306.0) mg. Dupilumab reduced the number of days of OCS use (mean [SD]) by 4.5% in the overall cohort and by 24.6% in the OCS-dependent group. The percentage of patients using OCS was reduced by 34.7% in the overall cohort ($P < 0.0001$) and by 20.6% in the OCS-dependent group ($P < 0.0001$). The percentage of patients using OCS for ≥ 90 days was reduced by 27.6% in the overall cohort ($P < 0.001$) and by 42% in the OCS-dependent group ($P < 0.0001$). The mean (SD) annualized cumulative OCS dose was reduced by 14.6% in the overall cohort ($P < 0.001$) and by 33.4%, to 2323.0 (2695.1) mg, in the OCS-dependent group ($P < 0.01$). **Conclusions:** Treatment with dupilumab reduced the number of days with OCS use, cumulative dose of OCS and the proportion of patients who used OCS ≥ 90 days, both in OCS-dependent and overall cohort population.



CO125

EFFICACY OF CLASCOTERONE CREAM 1% FOR UP TO 12 MONTHS IN PATIENTS ≥ 9 YEARS OF AGE WITH ACNE VULGARIS: RESULTS FROM A LONG-TERM EXTENSION STUDY

Eichenfield LF,¹ Hebert AA,² Stein Gold L,³ Cartwright M,⁴ Moro L,⁵

Han J,⁶ Squitieri N,⁷ Mazzetti A⁵

¹University of California, San Diego and Rady Children's Hospital, San Diego,

CA, USA, ²UT Health McGovern Medical School, Houston, TX, USA, ³Henry Ford

Medical Center, Detroit, MI, USA, ⁴Cassiopea Inc., San Diego, CA, USA,

⁵Cassiopea S.p.A., Lainate, Italy, ⁶Pharmapace, Inc., San Diego, CA, USA, ⁷San

Pharmaceutical Industries, Inc., Princeton, NJ, USA



Objectives: Clascoterone cream 1% is approved for the treatment of acne vulgaris in patients aged ≥ 12 years. Efficacy data from an open-label extension study are presented. **Methods:** The open-label, multicenter extension study (CB-03-01/27) enrolled male and female patients aged ≥ 9 years who completed one of the 12-week Phase 3 trials (CB-03-01/25 and CB-03-01/26) in patients with moderate-to-severe acne vulgaris. All patients applied 1% clascoterone cream twice daily to the face for 9 months; in the extension study, patients with truncal acne could also treat affected areas of the shoulders, chest, and/or back. Total time on clascoterone was up to 12 months for patients originally randomized to clascoterone in the Phase 3 trials. A 5-point Investigator's Global Assessment (IGA; 0, clear; 4, severe) was performed at extension Days 29, 85, 183, and 274; clascoterone treatment could be discontinued if IGA was 0 or 1 (IGA 0/1) and reinstated if/when acne worsened. Efficacy was analyzed in the intention-to-treat (ITT) population. **Results:** The ITT population included 609 patients, of whom 251 patients were treated for truncal acne. At baseline/Day 29/85/183/274, the proportion of ITT patients achieving facial IGA 0/1 was 9.9%/8.5%/10.1%/17.3%/29.8% and the proportion of ITT patients achieving truncal IGA 0/1 was 4.8%/17.1%/20.7%/25.9%/31.5%. In the ITT population, 539/417/304/123 patients used clascoterone for a total of 3/6/9/12 months. By total time on clascoterone, 13.1%/18.9%/39.2%/56.1% of ITT patients achieved facial IGA 0/1 and 13.6%/37.6%/43.4%/59.2% of ITT patients achieved truncal IGA 0/1 after 3/6/9/12 months on clascoterone treatment. **Conclusions:** Clascoterone cream 1% maintained a favorable efficacy profile for up to 12 months in patients aged ≥ 9 years with acne vulgaris.

CO127

ATOPIC MARCH AND COMORBIDITIES IN PATIENTS WITH ATOPIC DERMATITIS IN COLOMBIA

Laignelet H,¹ Ruiz J,² Reyes Sanchez JM,³ Castaño Gamboa N⁴

¹Gastrostep & Dermaloluciones SAS, Bogota, Colombia, ²Pfizer SAS, BOGOTA,

CUN, Colombia, ³Pfizer SAS, Bogota, CUN, Colombia, ⁴Pfizer SAS, Bogot,

Colombia

Objectives: To analyze the atopic march of atopic dermatitis (AD) in both children and adults and identify the risk factors associated with persistent clinical symptoms and associated atopic comorbidities. **Methods:** This retrospective observational study of patients with a confirmed diagnosis of AD from a dermatology reference center in Bogotá during 2011 to 2022. Patients were followed from the first visit in the dermatological center (index date), up to the last visit received at the center. Data on patient characteristics, treatment, comorbidities, and relapses were analyzed. Cumulative survival curves were generated to determine the time to first relapse using the Kaplan-Meier method. **Results:** A total of 208 patients had a mean age of 25 years, 64% were female, with a mean time of 17 years since diagnosis, 119 (57.2%) patients were classified as mild AD, 40 (19.2%) as moderate and 49 (23.5%) as severe. Main atopic comorbidities were allergic rhinitis (55.3%) and asthma (22.1%). One hundred twenty patients presented lesions in the facial area (57.7%), followed by folds in the extremities (111 cases). Most patients (93.2%) used topical corticosteroids and 63% had used topical calcineurin inhibitors. A total of 75.9% of the patients relapsed during the study period, the mean time to first relapse after index date for patients was 1.57 (95% CI 1.30-2.25) years. **Conclusions:** Results showed the heterogeneous nature of the disease and high variability of treatment trajectories of patients with AD within clinical practice.



CO130

DYSPNEA AND HEALTH-RELATED QUALITY OF LIFE IN PATIENTS WITH PERSISTENT SYMPTOMS AFTER AT LEAST SIX MONTHS OF HOSPITAL DISCHARGE DUE TO COVID-19

Lozano A,¹ Salcedo Mejia F,¹ Alvis Zakzuk NR,¹ Moyano L,¹

Jerez Arias M,² Paz Wilches J,³ Fernandez Mercado JC,⁴

Dueñas Castell C,⁵ Zakzuk Sierra J,⁶ Alvis Guzman N⁷

¹ALZAK Foundation, Cartagena, Colombia, ²Fundación SERSOCIAL IPS,

Cartagena, Colombia, ³Mutual SER EPS, Cartagena, Colombia, ⁴MUTUALSER

EPS - University of Cartagena - Clínica Crecer, Cali, VAC, Colombia,

⁵Universidad de Cartagena, Cartagena de Indias, Colombia, ⁶ALZAK

Foundation - Universidad de Cartagena, Cartagena, Colombia, ⁷ALZAK

Foundation- Universidad De La Costa, Barranquilla, Colombia

Objectives: To evaluate dyspnea in patients with persistent symptoms after at least six months of hospital discharge due to COVID-19 and its correlation with the quality of life, fatigue, and functional status. **Methods:** This cross-sectional study included 101 patients with persistent symptoms after at least six months of hospital discharge for COVID-19. A physician evaluated dyspnea using the Modified Medical Research Council (mMRC) scale questionnaire, the quality of life with the EQ-5D-5L, fatigue with an analog scale (0=no fatigue to 10=worst possible fatigue), and functional status with the Post-COVID-19 Functional Status scale (grade 0=no limitation to grade 4=severe limitation). We used Fisher's exact test for categorical data and the Wilcoxon rank-sum test for continuous data to assess differences across groups. Spearman's test was used for correlations. The significance level was 5%. **Results:** Of the participants, 56.4% (n=57) were women with a mean age of 57.7 (SD \pm 16.3) years. The most reported symptoms were muscle weakness (61.4%, n=62), dyspnea (51.5%, n=52), muscle pain (49.5%, n=50), and fatigue (41 (40.6%, n=41). Seventy-two (71.3%) participants reported an increase in the mMRC dyspnea scale score, with no differences according to ICU requirements. Forty of the 81 (49.4%) participants with an mMRC grade 0 before COVID-19 reported a grade 3-4 during the medical visit. The



EQ5D-5L index was 10% lower after COVID-19 (median difference: -0.01 points, interquartile range: -0.14 to -0.05), and those who required ICU admission had a more significant change in the index than those who did not (-0.12 vs -0.07, $p=0.008$). The mMRC grade reported during the medical visit was negatively correlated with the EQ5D-5L index ($\rho=-0.5836716$, $p<0.0001$) and positively correlated with fatigue ($\rho=0.38$, $p=0.001$) and functional status ($\rho=0.41$, $p<0.001$). **Conclusions:** Dyspnea is prevalent among patients discharge for COVID-19 with persistent symptoms and may affect their quality of life and functional status.

CO131

OFF PUMP CORONARY ARTERY BYPASS (OPCAB) VERSUS ON PUMP CORONARY ARTERY BYPASS GRAFTING (CABG) WITH CARDIOPULMONARY BYPASS; AN UMBRELLA REVIEW

Gopalan G,¹ Moinudeen S,² Rm K,³ Kachroo DK,⁴ Sharma J,⁵ Varalakshmi G⁶

¹Kalam Institute of Health Technology, AMTZ- A JBI Affiliated Group, Visakhapatnam, AP, India, ²Kalam Institute of Health Technology, AMTZ- A JBI Affiliated Group, Visakhapatnam, India, ³Kalam Institute of Health Technology, AMTZ- A JBI Affiliated group, Visakhapatnam, India, ⁴Kalam Institute of Health Technology, Visakhapatnam, India, ⁵Andhra Pradesh MedTech Zone, Andhra Pradesh, India, ⁶Andhra Pradesh Medical Technology Zone (AMTZ), Visakhapatnam, AP, India

Objectives: To assess the clinical effectiveness of OPCAB versus On- pump CABG surgery with Cardiopulmonary Bypass (CPB) in patients with coronary artery disease in terms of short- term mortality and other complications such as cerebrovascular accidents/ complications, renal complications/ injury, atrial fibrillation and myocardial infarction. **Methods:** Electronic databases were searched for published studies and systematic reviews and meta- analyses comparing OPCAB to CABG with Cardiopulmonary Bypass to assess the clinical effectiveness in terms of mortality and other complications were included. 22 reviews that met the eligibility criteria were then assessed for methodological quality using the AMSTAR- 2 tool and a narrative summary was given. **Results:** Two reviews were evaluated to be critically low, one review reported low quality, sixteen reviews reported moderate methodological quality and three reviews reported high quality. From the summary of findings tables, it was observed that there was a reduction in short term mortality rate, renal complications, cerebrovascular events, and rate of atrial fibrillation among patients who underwent OPCAB surgical technique as compared to on pump surgical technique. Though it was inconclusive of whether there was any significant difference between both groups for the rate of myocardial infarction. **Conclusions:** The clinical effectiveness as reported by the included reviews indicate that OPCAB is associated with lower rates of short- term mortality, renal complications, cerebrovascular events and atrial fibrillation as compared to on pump CABG. As for myocardial infarction, patients who underwent OPCAB are as likely to have myocardial infarction as those who underwent on pump CABG. Even though CPB costs an additional expense and the adverse events being high among patients, one cannot avoid employing CPB assistance when it is necessary, particularly when the patient's vital signs fall below the required range, or when the patient's lab results indicate a severe illness, or for other reasons.

CO132

PREDICTIVE VALIDITY OF PT-GLOBAL WEB-TOOL/PG-SGA, AND IMPACT OF MALNUTRITION ON RENAL OUTCOMES IN CHRONIC KIDNEY DISEASE PATIENTS: A HOSPITAL-BASED PROSPECTIVE COHORT

Rashid I,¹ Tiwari P,² D'Cruz S,³ Jaswal S⁴

¹National Institute of Pharmaceutical Education and Research (NIPER), Mohali, PB, India, ²National Institute of Pharmaceutical Education and Research (NIPER), Mohali, India, ³Government Medical College & Hospital (GMCH), Chandigarh, India, ⁴Government Medical College and Hospital, Chandigarh, India

Objectives: Dialysis dependence, end-stage renal disease, cardiovascular events, and all-cause mortality are a couple of negative clinical outcomes that have been demonstrated to be significantly associated with CKD progression. This study aimed to investigate the impact of malnutrition on renal outcomes in a prospective CKD cohort and also sought to determine the predictive validity of the Pt-Global web tool/PG-SGA. **Methods:** This prospective cohort study included non-dialysis CKD patients ($n=360$; aged 53.7 ± 13.9 years) with an index eGFR between the range of 15 and 89 ml/min/1.73 m². To assess nutritional status, it employed a "Pt-Global web tool/PG-SGA" whose predictive validity was ascertained using Receiver Operating Curves (ROC). The renal outcomes were evaluated as composite endpoints (commencement of dialysis, doubling of serum creatinine from the baseline, advancing to end-stage renal disease) and secondary outcomes (mortality). Kaplan-Meier plots were used to evaluate the cumulative survival, and Cox proportional hazard models were used to analyze the renal outcomes. **Results:** After a median follow-up of 14.0 ± 4.24 months. The incidence of mortality and composite endpoints were found to be 13.9% & 37.6%, respectively. Death rates (11.6%) and composite endpoints (29.8%) were higher in the malnourished (severe & moderate) group. Cox regression hazard model reported 4 times increased hazards for death [HR 4.41 (95% CI) 1.99-9.77, $P \leq 0.005$] and 3 times increased hazards for composite endpoints [HR 3.29 (95% CI) 2.10-5.16, $P \leq 0.005$] for 'severely malnourished' category (Q3) in reference to 'normal nutrition'

category (Q1). The ROC analysis showed that the AUC for the total PG-SGA score was 0.988 (95% CI: 0.976-1.000), indicating that it is a reliable indicator of malnutrition. **Conclusions:** The Pt-Global web tool/PG-SGA total score of 3 or more appears to be the ideal cut-off score for identifying malnutrition, which dieticians can utilize for improving malnutrition. Moreover, malnutrition was found to be a significant predictor of mortality for non-dialysis CKD patients.

CO133

CLINICAL AND ECONOMIC BURDEN ASSOCIATED WITH INTRAOPERATIVE HYPOTENSION AMONG HIGH-RISK SURGICAL PATIENTS IN TAIWAN: A RETROSPECTIVE COHORT STUDY

Chung CH,¹ Wang YJ,² Lee CY,² Hsu JY,³ Chen TI⁴

¹Mackay Medical College, New Taipei City,, Taiwan, ²Edwards Lifesciences, Taipei, Taiwan, ³Edwards Lifesciences, Taoyuan, TAO, Taiwan, ⁴Fu Jen Catholic University, New Taipei City, Taiwan

Objectives: Intraoperative Hypotension (IOH) was reported to associated with higher complication, cost and mortality after surgeries as compare with surgeries without IOH. Hypotension reduction may be associated with cost saving, specifically hospitalization. In this study, we aimed to determine the real-world IOH burden in Taiwan by using national health insurance database to understand the outcome difference in patients with or without IOH. **Methods:** Patients with inpatient record for ten selected surgical procedures between January 1, 2016, and December 31, 2019 from by using Taiwan National Health Insurance Research Database (NHIRD) were enrolled in this study. We compared the clinical and economic outcome difference between patients receiving surgeries with and without IOH. **Results:** The incremental average length of stay (LOS) in patients with IOH were ranged from 5.84-17.62 days as compare with patients without IOH. Almost all patients with IOH had significantly longer LOS than patients without IOH, except for abdominal aortic aneurysm open ($p = 0.0627$). The incremental average cost in patients with IOH were ranged from 3,296-10,858 USD as compare with patients without IOH. When compared with patients without IOH, all patients with IOH had significantly higher total costs. Almost all types of surgery had a significantly higher mortality rate in patients with IOH (HR ranged from 4.57 (4.25-4.92) to 11.77 (10.56-13.13)), except for abdominal aortic aneurysm open (2.73, 0.90-8.29). **Conclusions:** In this study, we found that IOH could be a risk factor to clinically significant perioperative side effects and higher mortality, potentially increasing healthcare costs. These findings suggest that preventing IOH could be as effective manner for side effects/mortality reduction during surgery and should be practiced as a safety precaution in the real world.

CO134

THE FUTURE OF COVID-19: WHAT IS NEXT IN THE DRUG PIPELINE

Carey A

National Prescription Drug Utilization Information System (NPDUI), Ottawa, ON, Canada

Objectives: Development of new and repurposed medicines in response to the COVID-19 pandemic has occurred at an unprecedented rate, resulting in a dynamic pipeline marked by significant challenges and successes. This analysis provides an overview of the vaccines and therapies undergoing clinical evaluation or with recent approval for the treatment and prevention of COVID-19 in global markets. **Methods:** For this analysis, COVID-19 pipeline medicines are defined in three categories: vaccines, new treatments and repurposed medicines. GlobalData is the primary data source for this study, in addition to online databases from Health Canada, the US FDA, and the EMA. International markets examined include the US and geographic Europe (excluding Russia and Turkey). **Results:** As of November 2022, the global pipeline contained over 600 therapies and vaccines undergoing Phase I, II, III clinical trials or pre-registration for the prevention and treatment of COVID-19. Preventive and repurposed medicines include antivirals, immunoglobulins, monoclonal antibodies, cellular therapies, and convalescent plasma. In Canada, twelve medicines, including six vaccines, have been approved for COVID-19. The number of global approvals is greater, with approximately 9 vaccines on the market in OECD countries. In addition to pre-exposure preventative therapies, manufacturers are also developing COVID-19 drugs to be used as prophylactic therapy. The analysis identifies new oral antiviral treatments and preventative therapies in the pipeline and under review in various jurisdictions globally. **Conclusions:** This research provides a clearer picture of the characteristics and evolution of the market for new and emerging COVID-19 medicines, which will help policy-makers and other stakeholders understand and anticipate the unique pressures of the COVID-19 pandemic.

CO135

CLINICAL AND ECONOMIC OUTCOMES ASSOCIATED WITH TRANSITIONS OF TOBACCO USE AMONG A COHORT OF ADULT MALE SMOKERS USING U.S. REAL-WORLD DATA

Zhang M,¹ Manjelievskaia J,² Noggle B,¹ Cheng H,¹ Richards M,³ Black D,⁴ Smith D,² Edmiston JS,¹ Rees A,¹ Gogova M¹

¹Altria Client Services LLC, Richmond, VA, USA, ²Merative, Cambridge, MA, USA, ³Merative, Ann Arbor, USA